

APPENDIX A
Inactionable Alleged Misstatements

FS ¹	Alleged Misstatement
Statements Expressing Confidence in and Potential of NDA Approval	
FS2	We look forward to working closely with both regulatory agencies throughout the review process and hope to bring the first treatment to patients with Galactosemia soon.
FS5	We look forward to continuing to work with the FDA throughout the review process, as we hope to bring govorestat to patients as quickly as possible.
FS8	As Applied enters into this next stage of growth, we are poised for continued value generation across our rare disease pipeline, supported by our recent financing and bolstered cash position.
FS12	While the PDUFA action date extension represents a delay, we remain confident in the potential for govorestat approval for Galactosemia and we will continue to work closely with the FDA throughout the review process.
FS13	I am pleased to welcome Dale to Applied, <u>particularly at this critical stage in the company's lifecycle as we approach the govorestat potential approval and launch...</u>
FS14	As we move towards becoming a commercial stage organization, we are committed to building out a strong and credentialed leadership team with experience launching rare disease therapies. I believe that Dale's breadth of experience in commercial leadership roles and proven track record with product launches will be invaluable in bringing Applied from a development company to a commercial organization.
FS18	Preparations are underway for the potential approval and commercial launch of govorestat for the treatment of Classic Galactosemia in the US and EU, following the significant regulatory progress we have already made in 2024.
FS21	Yes. So, <u>things are going very well with the FDA.</u>
FS22	In that time frame though, we have worked very successfully with them. We've been having some interesting conversations.
FS23	There's a lot of interactions with the FDA in the interim and that's all going very well and on track and we feel very encouraged.
FS28	And with Govorestat having a very positive safety profile, we think the risks are very low. And then we look to the benefit. And I think the benefit that we have demonstrated in our clinical studies is very clear and substantial, and clinically meaningful to parents and to patients. And so, we're very confident in the process and we're very hopeful that this will be the first drug approved for Galactosemia later this year.
FS29	It's been very positive and sort of normal course.
FS32	With potential approvals on the horizon, we are continuing to prepare for commercial launch of govorestat and have built a strong commercial and operational team.
FS33	We believe govorestat has the potential to greatly impact patients with Galactosemia, and <u>we look forward to potentially making this drug available to patients later this year in the U.S., and in early 2025 in the EU.</u>

¹ The statements alleged misleading in the Complaint are bolded and underlined and prefaced with {FS_} for numbering purposes. Compl. ¶78 n.2. For readability, we have only bolded and underlined where an alleged misstatement is limited to a portion of a sentence.

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FS34	We are at a pivotal time for the company with multiple key value-generating milestones upcoming. We look forward to providing regulatory updates this year for govorestat for the potential treatment of Classic Galactosemia and SORD Deficiency, both progressive rare diseases that represent significant opportunities to address patient needs.
FS38	At Applied, we are dedicated to creating transformative treatments for rare diseases, and <u>we continue to work closely with regulatory agencies and patient advocacy groups to ensure that treatments become available for patients with these debilitating diseases.</u>
FS42	So our drug, govorestat, which Brian mentioned, is under FDA and EMA review right now for a rare disease called galactosemia, <u>is advancing towards hopeful potential approval.</u>
FS43	Both indications, again have no treatments available, and <u>so this is an opportunity to be the first drug approved for both indications.</u>
FS44	I think we're in great shape, just noting that it's tentative and remains to be confirmed.
FS45	And that when there's an urgency to treat, as we believe is the case with galactosemia, it's a progressive disease, it affects children, there are no drugs approved, and we have a favorable safety and efficacy profile, our hope is that that same flexibility that they've shown with that last Advisory Committee meeting really applies to our program as well, and <u>we see an approval in galactosemia in the near term.</u>
FS46	<u>So we do feel that the review is going well where we should be,</u> but we're also being thoughtful and trying to right-size our organization to where we are at that point in time.
FS47	<u>So our goal is to be prepared for the launch and to take all the necessary steps that we should be doing now</u> without unnecessarily burning through capital and ensuring that we have a strong cash runway which we do.
FS48	<u>And so the way that we framed this is we waited until we felt sort of an additional derisking.</u> The mid-cycle review meeting was completed at the end of the spring. We've currently hired in all our heads of functions for commercial. While you might see that we're maybe posting for Salesforce, we've not hired a Salesforce yet. I think like a lot of companies, will wait till a little bit closer to the approval date to get that moving.
FS49	But I think we have the right level of commercial preparation happening as we move through the approval process and towards the launch.
FS50	I think that we're in really good shape with both programs. We're looking forward to the catalyst that we have ahead. I think it's a really important time for us as we hit the final stretch into approval of both of our programs. I think we're in a good place with regard to commercialization and being prepared for that big transition ahead of us from a development stage to a commercial-stage company. So I'm excited about what's ahead. I think we have a few really big things coming ahead, and we're excited.
FS51	We are incredibly pleased by the ongoing collaborative dialogue with the FDA during the NDA review process, and we look forward to continuing to work together with the agency to bring the first potential treatment to Classic Galactosemia patients.
FS52	Galactosemia is a progressive disease in urgent need of treatment, and <u>the potential approval of govorestat will be transformative for the many patients and families living with this serious disease. Our commitment to the Classic Galactosemia community is further supported by our thoughtful commercial preparation, focused on establishing an effective patient access program, high physician awareness and strong payor engagement.</u>
FS53	We're well capitalized and I think rightsized for where we are as an organization <u>and in the process of making that transition from clinical development stage to commercial stage company.</u>
FS55	And overall, our message there is that things are going well. We're very encouraged by the dialogue with FDA and we're excited about moving forward into this last stage of regulatory review.

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FS56	We are at that critical transition. As I mentioned, we're in the last phase of regulatory review right now and we're preparing for a potential commercial launch. Our PDUFA date with the FDA is November 28, which is Thanksgiving Day, so we have a couple of months. We have been preparing for quite a while now. We have a strong commercial team in place and medical field team.
FS57	Galactosemia which were in the sort of last leg of regulatory review with both the FDA and the EMA, and we're hopeful for a near term approval and launch. We're preparing diligently but thoughtfully for those commercial launches to make sure that we're set up for success, but that we remain well capitalized which is important to us. And I think we're in a very good place from a capitalization perspective.
FS58	And with the potential to have two indications launched on – and that synergy within our commercial infrastructure and sales force, I think we're very well set up for the future to be successful as a rare disease company and also to do something really meaningful for patients with these diseases.
FS60	We are proud of the significant progress we've made this quarter as we prepare for a transformational year ahead, with a focus on transitioning from a clinical-stage company to a commercial organization. With regulatory submissions for govorestat underway in two rare disease indications of urgent unmet need, Classic Galactosemia and SORD Deficiency, we continue to thoughtfully execute our pre-launch initiatives. . .
FS61	As we approach the final stages of the NDA review process for Classic Galactosemia in parallel with a near-term NDA submission for SORD Deficiency, we remain confident in the promise of govorestat and its ability to address the underlying mechanisms of both diseases. We look forward to the opportunity to bring govorestat to patients in 2025.
FS63	<u>We have a very late stage asset that's under regulatory review for one indication, classic Galactosemia and we're preparing for a regulatory submission for the second indication called SORD Deficiency. Both of these indications have the potential for near term commercial launches,</u> and we're well capitalized to bring us through these milestones.
FS66	And I'm sure everyone has noted our PDUFA date is right around the corner. So we have been preparing for commercial launch. We've taken steps that I think are appropriate, building a right sized and experienced commercial team.
FS69	So we have the potential to have two launches in very close proximity to one another and we've spent a lot of this year preparing for that. So I think we're very well prepared, we're in a good place to successfully launch in both of these indications and we're excited about the evolution of the company at this important time as we go from clinical stage to potentially commercial stage.
Statements Referencing Applied's Regulatory Progress	
FS4	The FDA's acceptance of the NDA for govorestat for the treatment of Galactosemia represents a critical milestone for Applied Therapeutics and more importantly, for patients with Galactosemia and their families. The Agency's decision to grant Priority Review for this NDA underscores the urgent unmet medical need as there are currently no treatment options for this devastating disease.
FS7	We've made significant clinical and regulatory progress, particularly with the NDA acceptance and MAA validation for govorestat for the treatment of Galactosemia, achieving key milestones for our rare disease pipeline.
FS18	Preparations are underway for the potential approval and commercial launch of govorestat for the treatment of Classic Galactosemia in the US and EU, following the significant regulatory progress we have already made in 2024.
FS37	Momentum continues with our steady regulatory progress in Classic Galactosemia and SORD Deficiency.
FS60	We are proud of the significant progress we've made this quarter as we prepare for a transformational year ahead, with a focus on transitioning from a clinical-stage company to a commercial organization. With regulatory submissions for govorestat underway in two rare disease indications of urgent unmet need, Classic Galactosemia and SORD Deficiency, we continue to thoughtfully execute our pre-launch initiatives . . .

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Statements Reiterating Facts	
FS64	And again it's currently under regulatory review in the U.S. and Europe for the treatment of classic Galactosemia. You'll note that our PDUFA date in the U.S. is November 28th, which is just a few weeks away and we're simultaneously under review in Europe and we're expecting a CHMP [Committee of Medicinal Products for Human Use] opinion in the first quarter of '25. . .
FS65	<u>And again, they're in the very late stages of regulatory review</u> and submission soon for SORD Deficiency. . .
FS67	So to sum up, govorestat is in late stage review and development for two rare diseases, Galactosemia and SORD Deficiency.
FS68	<u>For Galactosemia, we're under review at the FDA with a PDUFA date of November 28th this month</u> and our MAA is under review in Europe again expecting a CHMP decision in the first quarter of '25.